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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/723,544

Applicant(s)

SCHENK ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 14 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 69-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 69-95 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

The preliminary amendments filed 6-14-02 have been entered into the record and have been fully considered.

Claims 1-68 are canceled. Claims 69-95 are pending.

#### **Improper Markush**

Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed peptides or peptide components or methods would not be a reference against the other, nor necessarily render the inventions obvious. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not a proper genus or species.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 69-78 in part drawn respectively to chimeric peptides and immunogenic compositions of first and second portions, wherein the first portion is free N-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein

or a mature protein and the second portion comprises a T helper cell epitope classified for example in class 530, subclass 350.

- II. Claims 69-78 in part drawn respectively to chimeric peptides and immunogenic compositions of first and second portions, wherein the first portion comprises a T helper cell epitope and the second portion is a free C-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein or a mature protein classified for example in class 530, subclass 350.
- III. Claims 82-92 in part drawn to peptides of formula I, N-(S)m-(Th)n, classified in class 530, subclass 300.
- IV. Claims 82-92 in part drawn to peptides of formula II, (Th)n-(S)m-C, classified in class 530, subclass 300.
- V. Claims 79-81 and 93-95 in part drawn respectively to a method for immunization classified for example in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are related as products. The products are distinct each from the other as the products are comprised of divergent structure capable of different effects and function.

Inventions I-IV and V are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes for using the chimeric peptides can be practiced with alternative peptides as claimed and the products as claimed can be alternatively

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used in a method of treatment, a method of making antibodies, a method of screening compounds, and a method of detection.

Furthermore, in addition to the election of one of the above V groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

An internal cleavage product which is A) A $\beta$ 1-39, B) A $\beta$ 1-40, C) A $\beta$ 1-41, D) A $\beta$ 1-42, E) A $\beta$ 1-43, F) A $\beta$ 1-3, G) A $\beta$ 1-4, H) A $\beta$ 1-5, I) A $\beta$ 35-40, J) A $\beta$ 35-42., K) a free N-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein or a mature protein, wherein the protein is specified and L) a free C-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein or a mature protein, wherein the protein is specified.

A T helper cell epitope (Th) which is derived from A) tetanus toxoid, B) diphtheria toxoid, C) hepatitis B surface antigen, D) Malaria CS, E) E. coli toxoid, F) a toxoid from other pathogenic bacteria, G) SEQ ID NO: 45, H) SEQ ID NO:46, I) SEQ ID NO:49, and J) SEQ ID NO:50, which is K) promiscuous T helper cell epitope or is derived from L) tetanus toxin, M) diphtheria toxin, N) measles virus F protein, O) hepatitis B virus surface antigen, P) Chlamydia trachomatis major outer membrane protein, Q) Plasmodium falciparum circumsporozoite, R) Schistosoma mansoni triose phosphate isomerase, S) Escherichia coli TraT, or T-AM) SEQ ID NO: 8 to 27, respectively.

N which is the first A) 2, B) 3, C) 4, D) 5 amino acid residues from the free N-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein or a mature protein.

C which is the last A) 2, B) 3, C) 4, D) 5 amino acid residues from the free C-terminus of a naturally occurring internal peptide cleavage product derived from a precursor protein or a mature protein.

M is A) 0, B) 1, C) 2, D) 3, E) 4, or F) 5.

N is A) 1, B) 2, C) 3, or D) 4.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated above constitute patentably distinct inventions for the following reasons. Each of the chimeric peptides has a unique structural feature which requires a unique search of the prior art. The inventions indicated differ in structure and function as they are composed of divergent amino acids and are differentially able to bind and mediate biological functions. A reference to one peptide or element would not constitute a reference to another, nor necessarily render any peptide or element obvious. In addition, searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because the indicated searches are not co-extensive.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-V and a single molecular embodiment for each of designated peptide elements to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that neither I-V nor the peptide elements are species election requirements; rather each of I-V and the particular peptide elements are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.



Sharon L. Turner, Ph.D.

9/3/02